

### **REMARKS**

Claims 1-89 are pending in this application. New claims 82-89 are submitted herewith and find support in the specification (e.g., Table 5). Claims 1, 2, 14, 15, 27, 28 and 40 are amended.

Previously, in the original restriction requirement ("Restriction"), the Examiner alleged that the claims represent nine (Groups I to IX) inventions, and requires that a single group be elected for examination. In addition, the Examiner further asserts that if Group I is elected, Applicant must elect one marker from Table 1 and 5 or a specific combination thereof. (See, Action, page 7).

In reply, pursuant to 37 C.F.R. § 1.142, in response to the Restriction, in a reply filed July 12, 2007, Applicants elected Group I (claims 1-4, 6-7, 10-17, 19, 20, 23-30, 32-33, 36-43, 45-46 and 29-52), with traverse. Furthermore, claims 1, 2, 5, 14, 15, 27, 28 and 40 were amended to include that expression of a combination of two or more markers identified in Tables 1 and 5 are determined, thus providing a specific combination of markers.

In response, the Examiner submitted the Action mailed August 29, 2007 in which she alleged that the response was inadequate, and that a specific combination of two or three or four, etc., marker genes must be elected (OA, page 2, second paragraph). This requirement is respectfully traversed as discussed below.

### **Election with Traverse**

In order to be fully responsive Applicants have amended claims 1, 2, 5, 14, 15, 27, 28 and 40 to include particular marker genes (i.e., ABCC5, ERCC2 and GTF2H2).

However, Applicants respectfully assert that there is no undue search burden to examine a genus type claim (*see*, new claim 82) which require determining expression of any combination of marker genes identified Tables 1 and 5. Indeed, the Examiner need only search a total of 13 markers are identified in Tables 1 and 5, of which combinations can be utilized to diagnose cancer or assess anti-cancer therapeutics. The special technical feature is that such markers in any combination can be utilized in diagnostics and therapeutics of cancer (e.g., non-small cell lung cancer). As such each combination shares the same special technical feature.

The specification describes and fully supports selection of the particularly identified marker genes in diagnosis or treatment of cancer (e.g., Tables 1 and 5; page 56, lines 25-30).

Therefore, it is incorrect to assert, that the special technical feature linking Groups I-IX is the first nucleic acid listed in Table 1. Merely being the first listed marker does not constitute a special technical feature.

Moreover, as provided in the specification, the special technical feature between the various methods is that one or more combination of markers are better for diagnosis of cancer or for determining efficacy of a candidate therapeutic. (e.g., Specification, page 5, ll. 1-30). As such the various methods of the invention do share a single special technical feature which is not the first listed nucleic acid in Table 1.

In addition, it is important to note that by requiring the election of a single gene, or a specific combination of genes, the Examiner is inappropriately foreclosing the opportunity for Applicant to submit a genus type claim, where a combination of genes identified can be utilized. The assertion, that each of the marker genes is structurally or functionally distinct is irrelevant, because it implies that marker genes must for some unfounded reason be *structurally and functionally similar*. The claims are not direct to compositions of matter encompassing the 13 identified genes. Rather, the genus claims would be directed to a method for identifying an agent as affecting proliferation/death of cancer cells (e.g., claim 1) where expression levels of a gene or combination of genes in Table 1 or Table 5 are determinative. Thus, it is not clear why the Examiner appears to require that the genes be the same or similar. Moreover, the number of genes are so small, that it is respectfully asserted there would be no undue search burden .

In addition, the Examiner asserts that Groups I-VI and IX are drawn to different methods, by virtue of requiring different reagents and different active steps, and thus the methods do not share a special technical feature. (Action, p. 3 bottom). In reviewing the entirety of the applicable PCT rules, no support was found for such an assertion. The turnkey issue is not whether different reagents or action steps are required, but whether there is a shared special technical feature amongst different methods and/or compositions.

The distinction between Groups I and II is illustrative in demonstrating why the restriction requirement is inappropriate. The Examiner asserts that Group I and II require determining levels of nucleic acids and proteins respectively. (Action, p. 4, first paragraph).

In addition, the Examiner asserts that Group II requires diagnosing nonsmall cell lung cancer. On this latter assertion, it is presumed the Examiner intended to assert "Group III" (i.e., claims 53 and 54). As already discussed above, the special technical feature is that markers identified by Applicants are correlated to cancer diagnostics or therapeutics. Therefore, that one method (Group I) is directed to assessing expression levels via nucleic acid molecules and another by assessing protein levels (Group II) does not constitute a different special technical feature within the spirit and meaning of a single general inventive concept under PCT rule 13.1, because under PCT Rule 13.2, Groups I and II share the same or

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corresponding special technical feature, i.e., correlation of expression levels of markers in Table 1 and 5 in diagnosis or assessing anti-cancer therapeutics.

In sum, the various groups asserted by the Examiner do share a single special technical feature. As such it is respectfully requested that the restriction requirement as between Groups I-VI and IX be withdrawn and the corresponding claims be examined.

#### **CONCLUSION**


It is submitted that the present reply is fully responsive to the Examiner's request to elect a particular group of marker genes. Should the Examiner have any questions, please contact the undersigned attorney. The Commissioner is authorized to charge any additional fees, which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 31169.705.831).

Respectfully submitted,

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